UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,426	04/27/2006	Toshio Matsumoto	P29832	4734

7055 7590 07/31/2008

GREENBLUM & BERNSTEIN, P.L.C.
1950 ROLAND CLARKE PLACE
RESTON, VA 20191

EXAMINER
VO, HAI

ART UNIT	PAPER NUMBER
1794	

NOTIFICATION DATE	DELIVERY MODE
07/31/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com
pto@gbpatent.com

Office Action Summary	Application No.	Applicant(s)	
	10/577,426	MATSUMOTO ET AL.	
	Examiner	Art Unit	
	Hai Vo	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-12 and 14* is/are pending in the application.

4a) Of the above claim(s) *9-12 and 14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 4-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/04/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. The 102/103 art rejections over JP 03-065579 have been withdrawn in view of the present amendment and response. JP'579 does not teach the three-dimensional nanotunnel layers formed on wall surfaces of the fine pores of the substrate. However, upon further consideration, new ground of rejection is made in view of newly discovered reference to Kondo et al (US 4,626,392).

Information Disclosure Statement

2. The information disclosure statement filed 03/04/2008 fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 2, and 4-8 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The diameter of the fine pores of the substrate, porosity of the substrate and average thickness of the three-dimensional nanotunnel layers and average diameter of the nanotunnels together are critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The diameter of the fine pores of the substrate, the porosity of the substrate, average thickness of the three-dimensional nanotunnel layers, and average diameter of the nanotunnels together play a key role in capability of trapping the bone-forming protein and mechanical strength of the ceramic body.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1, 2, and 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 03-065579 in view of Kondo et al (US 4,626,392). JP'579 discloses a porous ceramic membrane comprising a calcium phosphate substrate having fine pores and a calcium phosphate coating on the substrate (pages 4 and 7). The coating contains 0.1 to 10% by weight of calcium phosphate that has a particle

size of 100 nm or less and Ca/P ratio of 1.5 to 1.666. The calcium phosphate particles of the coating have the rod-like shape and dimensions within the range disclosed in the specification of the present invention (page 9). The coating has an average thickness of 2 μm, which is within the claimed range (page 10). The porous ceramic membrane has pores with an average pore diameter ranging from 200 to 500 nm (page 10). The porous membrane is useful as an absorbent (page 11). Likewise, it is clearly apparent that at least some of the pores of the coating are communicated with those of the substrate for successful absorption. JP'578 teaches that the slurry is uniformly applied so as to form a uniform porous layer onto the substrate (page 8). Therefore, it is the examiner's position that the coating would be substantially formed on 100% of the wall surfaces of the fine pores of the substrate. JP'579 does not specifically disclose a method of immersing the substrate in a calcium phosphate slurry, followed by defoaming the slurry under reduced pressure so as to form three-dimensional nanotunnel layers in the fine pores inside the substrate. Kondo, however, teaches coating the surface of the porous ceramic substrate with a calcium phosphate base frit by spreading, immersion or spraying (column 3, lines 10-20). Kondo teaches a method of a method of immersing the porous ceramic substrate in a calcium phosphate slurry, followed by defoaming the slurry under reduced pressure (column 3, lines 50-55). This at least indicates that immersion and spraying have been shown in the art to be recognized processes for coating the surface of the porous ceramic substrate with the calcium phosphate. Therefore, it would have

been obvious to one having ordinary skill in the art at the time the invention was made to immerse the porous calcium phosphate substrate in a calcium phosphate slurry, followed by defoaming the slurry under reduced pressure as taught by Kondo because immersion and spraying have been shown in the art to be recognized processes for coating the surface of the porous ceramic substrate with the calcium phosphate. Likewise, the resulting ceramic body would have the three-dimensional nanotunnel layers formed in the fine pores inside the substrate.

7. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 03-065579 in view of Kondo et al (US 4,626,392) as applied to claim 1 above, and further in view of JP 2003-073182. JP'579 is silent as to the substrate having a porosity of 40 to 98%. JP'182, however, teaches a porous calcium phosphate substrate as a bone substitute material having a porosity of 5 to 50% and a Ca/P ratio ranging from 1.5 to 1.7 (paragraphs 13 and 15). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the porous calcium phosphate substrate having a porosity as taught by JP'182 motivated by the desire to porous ceramic membrane with sufficient strength. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the porous calcium phosphate substrate having a Ca/P ratio as taught by JP'182 motivated by the desire to produce the substrate having desired amount of hydroxyapatite having excellent biocompatility for use as a bone substitute material.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hai Vo whose telephone number is (571) 272-1485. The examiner can normally be reached on Monday through Thursday, from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye can be reached on (571) 272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Hai Vo/
Primary Examiner, Art Unit 1794